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REMARKS

In view of the above amendments and following remarks, reconsideration of the objections and rejections contained in the Office Action of November 3, 2004 is respectfully requested.

The Examiner's note regarding the numbering of the claims is acknowledged. The Examiner's numbering has been employed above.

The Examiner's objection to trademarks and their use is respectfully traversed. The Examiner initially notes that the trademarks are have not been capitalized. By the above amendments, accordingly, each of TachoComb®, TachoComb® H and Tachotop® have all been capitalized. By the above amendments, further, they are accompanied by the generic terminology of "hemostatic collagen sponge."

The Examiner's statement that the specification should include published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred to by the trademarks is further traversed. For example, with respect to TachoComb® as described at the top of page 2 of the original specification, reference is made to EP 0 059 265. Further, it is not seen where there is any requirement for the specification to include this information. In addition, the Examiner's attention is directed to accompanying Attachment A, which is a Summary of Product Characteristics for TachoComb®H. Also note the accompanying Summary of Product Characteristics for TachoComb®, Attachment B, and for Tachotop®, Attachment C (in German only).

The Examiner's rejection of claims 7, 8, 10 and 11 as being indefinite is respectfully traversed. These claims have now been amended to address the concerns raised by the Examiner. Note the addition of new claims 41-44 setting forth as further dependent claims the various "such as" limitations.

The Examiner rejected claims 1-34 as being unpatentable over Kokai Japanese Unexamined Patent Publication No. 7-59812 in view of GB Patent No. 1 292 326 and WO 99/13902. However,

it is respectfully submitted that claims 1-34 and claims 41-44 clearly patentably distinguish over each of these references, particularly as amended above.

By the above amendments, both independent claims 1 and 34 have been amended to recite that the drying of the collagen foam obtains a dry block of collagen sponge having a three-dimensional structure with stacked chambers which are separated and substantially totally enclosed by walls of collagen material. Note for example the description on page 5 of the original specification. Thus with the method according to the present invention, a collagen sponge is prepared that is air and liquid tight in the sense that, once the collagen sponge has been applied to the wound, it will not allow air or liquid to pass through the collagen sponge. Liquids are absorbed in the sponge.

In general, the present invention relates to the problem of providing a method for producing a collagen sponge that is liquid and/or air tight and that may efficiently absorb air and/or liquid, while being suitable for being coated with a fibrin glue preparation so as to obtain a material for healing and sealing wounds. This problem is resolved by mixing and drying the collagen foam so that the sponge obtained has the chamber structure as recited in claims 1 and 34. The successful coating of the collagen with fibrin glue preparation will depend upon the texture of the collagen sponge. Note lines 19-23 of page 4 of the original specification. The texture of the sponge also impacts the absorbing and closing characteristics of the sponge.

JP No. 7-59812 discloses a method for producing a wound cover material in which a collagen sponge structure or body has a honeycomb structure. Air bubbles are controlled to a diameter within the range of 50-2,000 μm , which bubbles communicate straight from one surface to the other surface. Thus formed are cells that communicate straight from one surface to the other surface, obtaining a wound cover material that facilitates the exudation of liquid leaching out of the inside of the body, particularly on the wound surface. The cells are formed by straight water columns in a gelatinous body by exposing an acidic solution of collagen to ammonia gas, and subsequently volatilizing the moisture inside the gel by freeze-drying.

Thus, in addition to the differences already mentioned by the Examiner between claims 1 and 34 and the Japanese publication, the Japanese reference also clearly fails to disclose or suggest any

method that would result in a collagen sponge with a chamber structure with stacked chambers that are separated and substantially totally enclosed by walls of collagen material.

The collagen sponge that is obtained by the present invention of claims 1 and 34 has the chambers substantially totally enclosed by walls of the collagen material. In other words, the collagen sponge does not have bubbles that communicate all the way from surface of the material to the other surface of the material, i.e. through-going channels, as in the Japanese reference.

The Examiner acknowledges a number of additional differences between the Japanese publication and claims 1 and 34, but refers to the British patent and the WO reference. However, the British patent is completely silent with respect to the texture of the collagen product. The WO reference does not relate to collagen sponges having chamber diameters in the range of the collagen sponge according to the present invention, furthermore. As such, one of skill in the art would find no suggestion or reason to combine these references so as to arrive at the method of claims 1 and 34. Indeed, the problems that underlie the present invention are neither recognized nor solved by any of these three references.

In noting the Examiner's rejection, it is instructive to note that there is no reason for combining the British patent or the WO reference cited by the Examiner. Indeed, there is no suggestion of any combination with the Japanese publication. There is no indication that any improvement or benefit would be achieved by such consideration of the combination of the references.

The Examiner's consideration of the various specific pH's, temperatures, diameters, dimensions, percentages of collagen content, viscosity, duration of time for storage, homogenizing, neutralizing, and drying, percentage of lactic acid, gel content, water content, etc. as being suggested by the prior art because there are some overlap of ranges fails to present a *prima facie* case of obviousness. There is no sufficient teaching from any of these references to arrive at the specific requirements according to the claims of the present application. None of the references cited by the Examiner have either the purpose or the specific steps of the present invention. Thus, there is no reasoning or motivation to make any such combination.


Further, the Examiner's consideration of these parameters as simply being the optimization of cause effective variables is traversed. The Examiner has not identified where in the prior art it is taught that these are all cause effective variables to be considered in a method of preparing a collagen sponge. In short, the Examiner's rejection is largely conclusionary without sufficient evidence to support the conclusions.

Accordingly, withdrawal of the prior art rejections is submitted to be in order, and such withdrawal is respectfully requested.

In view of the above amendments and remarks, it is submitted that the present application is now in condition for allowance, and the Examiner is requested to pass the case to issue. If the Examiner should have any comments or suggestions to help speed the prosecution of this application, the Examiner is requested to contact Applicant's undersigned representative.

Respectfully submitted,

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